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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,018	03/16/2001	James Robl	P 0279159	6620

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EXAMINER

TON, THAIAN N

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 04/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/809,018	Applicant(s) ROBL ET AL.	
	Examiner Thaia N. Ton	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-25 and 32-35, drawn to methods of producing embryonic or stem-like cells, embryonic or stem-like cells, differentiated human cells, classified in class 800, subclass 8+, for example.
- II. Claims 26-28 and 31, drawn to a method of therapy comprising administering to a patient in need differentiated human cells, wherein the disease is Huntington's disease, classified in class 514, subclass 44.
- III. Claims 26-28 and 31, drawn to a method of therapy comprising administering to a patient in need differentiated human cells, wherein the disease is Alzheimer's disease, classified in class 514, subclass 44.
- IV. Claims 26-28 and 31, drawn to a method of therapy comprising administering to a patient in need differentiated human cells, wherein the disease is ALS, classified in class 514, subclass 44.
- V. Claims 26-28 and 31, drawn to a method of therapy comprising administering to a patient in need differentiated human cells, wherein the disease is spinal cord defects or injuries, classified in class 514, subclass 44.
- VI. Claims 26-28 and 31, drawn to a method of therapy comprising administering to a patient in need differentiated human cells, wherein the disease is multiple sclerosis, classified in class 514, subclass 44.
- VII. Claims 26-28 and 31, drawn to a method of therapy comprising administering to a patient in need differentiated human cells, wherein the disease is muscular dystrophy, classified in class 514, subclass 44.
- VIII. Claims 26-28 and 31, drawn to a method of therapy comprising administering to a patient in need differentiated human cells, wherein the disease is cystic fibrosis, classified in class 514, subclass 44.

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- IX. Claims 26-28 and 31, drawn to a method of therapy comprising administering to a patient in need differentiated human cells, wherein the disease is liver disease, classified in class 514, subclass 44.
- X. Claims 26-28 and 31, drawn to a method of therapy comprising administering to a patient in need differentiated human cells, wherein the disease is diabetes, classified in class 514, subclass 44.
- XI. Claims 26-28 and 31, drawn to a method of therapy comprising administering to a patient in need differentiated human cells, wherein the disease is heart disease, classified in class 514, subclass 44.
- XII. Claims 26-28 and 31, drawn to a method of therapy comprising administering to a patient in need differentiated human cells, wherein the disease is cartilage defects or injuries, classified in class 514, subclass 44.
- XIII. Claims 26-28 and 31, drawn to a method of therapy comprising administering to a patient in need differentiated human cells, wherein the disease is burns, classified in class 514, subclass 44.
- XIV. Claims 26-28 and 31, drawn to a method of therapy comprising administering to a patient in need differentiated human cells, wherein the disease is foot ulcers, classified in class 514, subclass 44.
- XV. Claims 26-28 and 31, drawn to a method of therapy comprising administering to a patient in need differentiated human cells, wherein the disease is vascular disease, classified in class 514, subclass 44.
- XVI. Claims 26-28 and 31, drawn to a method of therapy comprising administering to a patient in need differentiated human cells, wherein the disease is urinary tract disease, classified in class 514, subclass 44.
- XVII. Claims 26-28 and 31, drawn to a method of therapy comprising administering to a patient in need differentiated human cells, wherein the disease is AIDS, classified in class 514, subclass 44.
- XVIII. Claims 26-29 and 31, drawn to a method of therapy comprising administering to a patient in need differentiated human cells, wherein the disease is Parkinson's disease and the differentiated cells are neural cells, classified in class 514, subclass 44.

- XIX. Claim 26-28, 30 and 31, drawn to a method of therapy comprising administering to a patient in need differentiated human cells, wherein the disease is cancer and the differentiated cells are hematopoietic cells, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Invention I and any of Inventions II-XIX are distinct and of separate use. Invention I is drawn to methods of producing embryonic or stem-like cells, whereas Inventions II-XIX are drawn to methods of therapy. Furthermore, the methods used to make the embryonic or stem-like cells are patentably distinct from the methods of therapy of Inventions II-XIX. Each of the methods requires a materially different and separate protocol.

Invention II and any of Inventions III-XIX are mutually exclusive and independent. The method of therapy comprising administering differentiated human cells to a patient suffering from Huntington's disease of Invention II is not required for the methods of administering differentiated human cells to a patient suffering from: Alzheimer's disease of Invention III, ALS of Invention IV, spinal cord injuries or defects of Invention V, multiple sclerosis of Invention VI, muscular dystrophy of Invention VII, cystic fibrosis of Invention VIII, liver disease of Invention IX, diabetes of Invention X, heart disease of Invention XI, cartilage defects or injuries of Invention XII, burns of Invention XIII, foot ulcers of Invention XIV, vascular disease of Invention XV, urinary tract disease of Invention XVI, AIDS of Invention XVII, Parkinson's disease of Invention XVIII or cancer of Invention

XIX, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Invention III and any of Inventions IV-XIX are mutually exclusive and independent methods. The method of therapy comprising administering differentiated human cells to a patient suffering from Alzheimer's disease of Invention III is not required for the methods of administering differentiated human cells to a patient suffering from: ALS of Invention IV, spinal cord injuries or defects of Invention V, multiple sclerosis of Invention VI, muscular dystrophy of Invention VII, cystic fibrosis of Invention VIII, liver disease of Invention IX, diabetes of Invention X, heart disease of Invention XI, cartilage defects or injuries of Invention XII, burns of Invention XIII, foot ulcers of Invention XIV, vascular disease of Invention XV, urinary tract disease of Invention XVI, AIDS of Invention XVII, Parkinson's disease of Invention XVIII or cancer of Invention XIX, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Invention IV and any of Inventions V-XIX are mutually exclusive and independent methods. The method of therapy comprising administering differentiated human cells to a patient suffering from ALS of Invention IV is not required for the methods of administering differentiated human cells to a patient suffering from: spinal cord injuries or defects of Invention V, multiple sclerosis of Invention VI, muscular dystrophy of Invention VII, cystic fibrosis of Invention VIII,

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liver disease of Invention IX, diabetes of Invention X, heart disease of Invention XI, cartilage defects or injuries of Invention XII, burns of Invention XIII, foot ulcers of Invention XIV, vascular disease of Invention XV, urinary tract disease of Invention XVI, AIDS of Invention XVII, Parkinson's disease of Invention XVIII or cancer of Invention XIX, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Invention V and any of Inventions VI-XIX are mutually exclusive and independent methods. The method of therapy comprising administering differentiated human cells to a patient suffering from spinal cord injuries or defects of Invention V is not required for the methods of administering differentiated human cells to a patient suffering from: multiple sclerosis of Invention VI, muscular dystrophy of Invention VII, cystic fibrosis of Invention VIII, liver disease of Invention IX, diabetes of Invention X, heart disease of Invention XI, cartilage defects or injuries of Invention XII, burns of Invention XIII, foot ulcers of Invention XIV, vascular disease of Invention XV, urinary tract disease of Invention XVI, AIDS of Invention XVII, Parkinson's disease of Invention XVIII or cancer of Invention XIX, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Invention VI and any of Inventions VII-XIX are mutually exclusive and independent methods. The method of therapy comprising administering differentiated human cells to a patient suffering from multiple sclerosis of Invention

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VI is not required for the methods of administering differentiated human cells to a patient suffering from: muscular dystrophy of Invention VII, cystic fibrosis of Invention VIII, liver disease of Invention IX, diabetes of Invention X, heart disease of Invention XI, cartilage defects or injuries of Invention XII, burns of Invention XIII, foot ulcers of Invention XIV, vascular disease of Invention XV, urinary tract disease of Invention XVI, AIDS of Invention XVII, Parkinson's disease of Invention XVIII or cancer of Invention XIX, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Invention VII and any of Inventions VIII-XIX are mutually exclusive and independent methods. The method of therapy comprising administering differentiated human cells to a patient suffering from muscular dystrophy of Invention VII is not required for the methods of administering differentiated human cells to a patient suffering from: cystic fibrosis of Invention VIII, liver disease of Invention IX, diabetes of Invention X, heart disease of Invention XI, cartilage defects or injuries of Invention XII, burns of Invention XIII, foot ulcers of Invention XIV, vascular disease of Invention XV, urinary tract disease of Invention XVI, AIDS of Invention XVII, Parkinson's disease of Invention XVIII or cancer of Invention XIX, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Invention VIII and any of Inventions IX-XIX are mutually exclusive and independent methods. The method of therapy comprising administering

differentiated human cells to a patient suffering from cystic fibrosis of Invention VIII is not required for the methods of administering differentiated human cells to a patient suffering from: liver disease of Invention IX, diabetes of Invention X, heart disease of Invention XI, cartilage defects or injuries of Invention XII, burns of Invention XIII, foot ulcers of Invention XIV, vascular disease of Invention XV, urinary tract disease of Invention XVI, AIDS of Invention XVII, Parkinson's disease of Invention XVIII or cancer of Invention XIX, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Invention IX and any of Inventions X-XIX are mutually exclusive and independent methods. The method of therapy comprising administering differentiated human cells to a patient suffering from liver disease of Invention IX is not required for the methods of administering differentiated human cells to a patient suffering from: diabetes of Invention X, heart disease of Invention XI, cartilage defects or injuries of Invention XII, burns of Invention XIII, foot ulcers of Invention XIV, vascular disease of Invention XV, urinary tract disease of Invention XVI, AIDS of Invention XVII, Parkinson's disease of Invention XVIII or cancer of Invention XIX, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Invention X and any of Inventions XI-XIX are mutually exclusive and independent methods. The method of therapy comprising administering differentiated human cells to a patient suffering from diabetes of Invention X is not

required for the methods of administering differentiated human cells to a patient suffering from: heart disease of Invention XI, cartilage defects or injuries of Invention XII, burns of Invention XIII, foot ulcers of Invention XIV, vascular disease of Invention XV, urinary tract disease of Invention XVI, AIDS of Invention XVII, Parkinson's disease of Invention XVIII or cancer of Invention XIX, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Invention XI and any of Inventions XII-XIX are mutually exclusive and independent methods. The method of therapy comprising administering differentiated human cells to a patient suffering from heart disease of Invention XI is not required for the methods of administering differentiated human cells to a patient suffering from: cartilage defects or injuries of Invention XII, burns of Invention XIII, foot ulcers of Invention XIV, vascular disease of Invention XV, urinary tract disease of Invention XVI, AIDS of Invention XVII, Parkinson's disease of Invention XVIII or cancer of Invention XIX, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Invention XII and any of Inventions XIII-XIX are mutually exclusive and independent methods. The method of therapy comprising administering differentiated human cells to a patient suffering from cartilage defects or injuries of Invention XII is not required for the methods of administering differentiated human cells to a patient suffering from: burns of Invention XIII, foot ulcers of Invention

XIV, vascular disease of Invention XV, urinary tract disease of Invention XVI, AIDS of Invention XVII, Parkinson's disease of Invention XVIII or cancer of Invention XIX, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Invention XIII and any of Inventions XIV-XIX are mutually exclusive and independent methods. The method of therapy comprising administering differentiated human cells to a patient suffering from burns of Invention XIII is not required for the methods of administering differentiated human cells to a patient suffering from: foot ulcers of Invention XIV, vascular disease of Invention XV, urinary tract disease of Invention XVI, AIDS of Invention XVII, Parkinson's disease of Invention XVIII or cancer of Invention XIX, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Invention XIV and any of Inventions XV-XIX are mutually exclusive and independent methods. The method of therapy comprising administering differentiated human cells to a patient suffering from foot ulcers of Invention XIV is not required for the methods of administering differentiated human cells to a patient suffering from: vascular disease of Invention XV, urinary tract disease of Invention XVI, AIDS of Invention XVII, Parkinson's disease of Invention XVIII or cancer of Invention XIX, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Invention XV and any of Inventions XVI-XIX are mutually exclusive and independent methods. The method of therapy comprising administering differentiated human cells to a patient suffering from vascular disease of Invention XV is not required for the methods of administering differentiated human cells to a patient suffering from: urinary tract disease of Invention XVI, AIDS of Invention XVII, Parkinson's disease of Invention XVIII or cancer of Invention XIX, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Invention XVI and any of Inventions XVII-XIX are mutually exclusive and independent methods. The method of therapy comprising administering differentiated human cells to a patient suffering from urinary tract disease of Invention XVI is not required for the methods of administering differentiated human cells to a patient suffering from: AIDS of Invention XVII, Parkinson's disease of Invention XVIII or cancer of Invention XIX, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Invention XVII and either of Inventions XVIII-XIX are mutually exclusive and independent methods. The method of therapy comprising administering differentiated human cells to a patient suffering from AIDS of Invention XVII is not required for the methods of administering differentiated human cells to a patient suffering from: Parkinson's disease of Invention XVIII or cancer of Invention XIX,

and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Invention XVIII and Inventions XIX are mutually exclusive and independent methods. The method of therapy comprising administering differentiated human cells to a patient suffering from Parkinson's disease of Invention XVIII is not required for the methods of administering differentiated human cells to a patient suffering from cancer of Invention XIX, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Patsy Zimmerman, Patent Analyst, at (703) 305-2758. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

Deborah Crouch

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